

Docket No.: 209060US0

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
ISABELLE AFRIAT : EXAMINER: L. WELLS
SERIAL NO: 09/884,949 :
FILED: JUNE 21, 2001 : GROUP ART UNIT: 1617
FOR: COMPOSITION IN THE FORM OF A
WATER-IN-OIL EMULSION WITH
A VARIABLE SHEAR RATE AND
METHODS OF USING THE SAME

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Appellant submits this brief in response to the Final Rejection dated October 23,
2003.

REAL PARTY IN INTEREST

The real party in interest herein is L'Oréal S.A. of Paris, France.

RELATED APPEALS AND INTERFERENCES

To the best of Appellant's knowledge, there are no other appeals or interferences
which will directly affect or be directly affected by, or have a bearing on, the Board's decision
in this appeal.

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STATUS OF CLAIMS

Claims 1-29 are pending.

STATUS OF AMENDMENTS

All amendments, declarations and remarks filed in this case have been entered and considered.

SUMMARY OF INVENTION

The invention relates to water-in-oil emulsions containing at least 80% by weight aqueous phase and a dimethicone copolyol emulsifier. (Specification at page 4, line 22 et seq.). In the invention compositions, the oily phase and the dimethicone copolyol emulsifier are present in a weight ratio greater than or equal to 5. (Specification at page 5, lines 1-2). Moreover, the dimethicone copolyol emulsifier contains only oxyethylene groups as oxyalkylene groups. (Specification at page 5, lines 2-3). Additionally, the invention compositions can be in a physiologically acceptable medium. (Specification at page 5, lines 4-6).

The invention compositions can be used in methods for treating, protecting, caring for, removing make-up from and/or cleansing the skin, the lips and/or the hair, and/or for making up the skin and/or the lips, (specification at page 4, lines 6-9), as well as in methods for treating, protecting, caring for, removing make-up from, making up, and/or cleansing greasy skin. (Specification at page 4, lines 10-12).

ISSUE

1. Whether The Pending Claims Are Obvious Over Mellul.

GROUPING OF CLAIMS

The claims do not stand or fall together. Each claim stands individually, and in the argument section provided below Appellant explains why the claims are each separately patentable, one from the other.

ARGUMENT

The claims require the presence of (1) a water-in-oil (W/O) emulsion; (2) a dimethicone copolyol emulsifier comprising only oxyethylene groups as oxyalkylene groups; (3) an aqueous phase of at least 80% by weight; **and** (4) a weight ratio of oily phase to emulsifier of greater than or equal to 5. The invention compositions, despite their high water content, are stable even when stored under conditions of fluctuating temperatures. (Page 3, lines 19-21). Moreover, the invention compositions have rheological characteristics such that, when applied to skin, the composition “breaks” (that is, suddenly becomes fluid under the effect of shear), thereby providing great freshness. (Page 4, lines 1-2).

Mellul neither teaches nor suggests the invention compositions, or any stability or “break” benefits associated with such compositions.

Mellul does not exemplify oil-in-water emulsions containing at least 80% aqueous phase, the required dimethicone copolyol emulsifier and the required oily phase to

dimethicone copolyol emulsifier weight ratio. For example, Mellul exemplifies compositions having, at most, 70% aqueous phase. (See, example 24). Moreover, Mellul would not lead one skilled in the art to select and combine all of these required elements in such a way to arrive at the invention compositions.

Mellul does not attach any special significance to having 80% or more aqueous phase. Thus, according to Mellul, 70% aqueous phase is no different from 80% aqueous phase. However, as indicated in the numerous Rule 132 declarations submitted in this case, a “surprising and unexpected difference” exists between compositions having 70% aqueous phase and the invention compositions having 80% aqueous phase with respect to “break” properties.

Moreover, Mellul does not attach any special significance to using silicone emulsifiers which are dimethicone copolyols comprising only oxyethylene groups as oxyalkylene groups. In her discussion of acceptable silicone surfactants, Mellul includes surfactants containing oxyethylenated groups as well as oxypropylenated groups. (See, for example, col. 8, line 11, et. seq., particularly line 23). However, as shown in the examples of the present specification, silicone emulsifiers containing oxyethylenated groups and oxypropylenated groups do not possess good stability under fluctuating temperature conditions. In contrast, the invention compositions containing dimethicone copolyol emulsifiers comprising only oxyethylene groups as oxyalkylene groups have good stability under such conditions.

Based on Mellul's disclosure, one skilled in the art would not have been motivated to selectively combine elements so as to produce W/O emulsions containing (1) 80% or more aqueous phase, (2) a dimethicone copolyol emulsifier comprising only oxyethylene groups as

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oxyalkylene groups and (3) an oily phase to silicone emulsifier weight ratio greater than or equal to 5 with the expectation that any special properties would result from such a selective combination. In other words, Mellul does not provide any guidance or motivation which would lead one skilled in the art to the invention compositions. Accordingly, no *prima facie* case of obviousness exists and the § 103 rejection should be withdrawn.

Even assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness --which she has not-- the numerous Rule 132 declarations submitted in this case and the examples in the specification are more than sufficient to overcome such a hypothetical *prima facie* showing. The declarations demonstrate that W/O emulsions containing 80% or more aqueous phase, the required dimethicone copolyol emulsifier and the required oily phase to emulsifier weight ratio "unexpectedly and surprisingly" break more readily than emulsions containing less aqueous phase, meaning that the former compositions have more aqueous phase available for contact with skin than the latter emulsions. The declarations indicate that this difference is significant because it provides W/O emulsions having 80% or more aqueous phase a fresher feeling upon application, an important characteristic in the cosmetic field.

The declarations also demonstrate that compositions corresponding to Mellul's Example 24, the example upon which the Examiner focused during prosecution (see, Office Action dated January 24, 2002, at page 3), are unsuitable for use in the cosmetic industry, unlike the claimed invention.

Finally, the examples in the present specification demonstrate that compositions containing the required dimethicone copolyol emulsifier are more stable under fluctuating

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temperature conditions than compositions containing other silicone emulsifiers containing oxyethylenated groups and oxypropylenated groups, making the former compositions better suited for commercial production, storage and transport than the latter compositions.

In view of the improved rheological characteristics of the invention compositions demonstrated in the numerous Rule 132 declarations submitted in this case, as well as the compositions' improved stability under fluctuating temperature conditions demonstrated in the present application, Appellant submits that the invention compositions are not obvious and, thus, deserving of patent protection.

Finally, Appellant notes that during the Interview conducted April 8, 2004, the Examiner orally indicated that Appellant had made a sufficient showing of unexpected results for compositions containing 85% or more aqueous phase. (See, Request for Reconsideration filed June 3, 2004). However, the Examiner indicated that Appellant had not made a sufficient showing for compositions containing 80% aqueous phase.

In response to the Examiner's comments during the Interview, Appellant submitted her fifth Rule 132 declaration demonstrating that W/O emulsions containing 80% aqueous phase yielded "surprising and unexpected" results, thereby addressing the Examiner's final concern relating to Appellant's demonstration of unexpected results for the invention compositions. The case should have been in condition for allowance at that point.

However, in the subsequent Advisory Action (dated July 8, 2004), the Examiner indicated that the five Rule 132 declarations submitted in this case did not overcome the §103 rejection based on Mellul (1) for the reasons already of record; (2) because the declarations are not commensurate in scope with the claims (specifically, the claims encompass emulsions

containing any oil phase, whereas the declarations are directed compositions containing specific oils); and (3) the declarations are directed to methods, whereas the claims are directed to compositions.

Regarding (1), the record is clear that Appellant has addressed each concern raised by the Examiner relating to the Rule 132 declarations submitted in this case. A copy of each declaration is attached hereto at Tabs 1-5. Specifically, the declarations demonstrate:

1. July 24, 2002: This declaration demonstrates that W/O emulsions containing 80% or more aqueous phase and the claimed silicone emulsifier "break" more readily than W/O emulsions containing less aqueous phase (70% aqueous phase). This ability to "break" indicates that compositions having 80% or more aqueous phase possess better fluidization properties and, hence, provide greater freshness upon application to skin than emulsions containing less aqueous phase, a "surprising and unexpected difference" between these emulsions.

The declaration also demonstrates that W/O emulsions corresponding to Mellul's example 24 are unacceptable for use in the cosmetic industry (that is, they are crude pastes), whereas the claimed compositions are cream products suitable for use in cosmetics. This difference was "surprising and unexpected."

2. March 10, 2003: In response to the Examiner asserting that the July 24, 2002, declaration was not persuasive¹ because the graphs accompanying the declaration

¹ The Examiner also asserted that the July 24 declaration was unpersuasive because the

were unclear because they were not labeled and because it was unclear what the different lines represent, this declaration explains that the graphs depict shear rates as a function of time for various applied shear stresses, and that the graph for the comparative example CM 3/5 contains flat lines at each of the applied shear stresses. The declaration goes on to explain that these flat lines indicate that evolution of shear rates does not occur upon application of the shear stresses, meaning that the comparative composition CM 3/5 does not readily "break" or become fluid, but that the lines for the compositions of the present invention are not flat, indicating that these compositions break much more readily than the comparative example.

3. August 18, 2003: In response to the Examiner's asserting that the two previous declarations were not commensurate in scope with the claims in two new respects: (a) Applicant provided only one example of a W/O emulsion containing 80% or greater aqueous phase; and (b) the claimed compositions did not break when shear stress of 100-349 Pa is applied, this declaration demonstrates that W/O emulsions containing aqueous phases of greater than 80% [89.5% (658463-2) and 90.55% (658463-3)] readily break.

This declaration also explains that because W/O emulsions did not readily break at shear rates of 1-349 Pa does not lead to the conclusion that the claims are not commensurate in scope with Appellant's showing. Shear stress forces to which W/O

claims were not commensurate in scope with the declaration (as well as the examples in the specification) because the claims do not require an electrolyte or glycerol in the aqueous phase. This assertion was overcome with argument.

emulsions are typically subject upon application to skin range from 100-1000 Pa.

What is important for purposes of "breaking" is that the emulsion breaks at some point in the 100-1000 Pa range, not that it break throughout the entire range. The significant point from the experimental data discussed in the previous declarations is that the claimed W/O emulsions readily break when applied to skin at shear stress forces to which W/O emulsions are typically subject upon such application (100-1000 Pa), whereas comparative examples do not.

4. January 23, 2004: This declaration responds to several Examiner assertions as follows.

Regarding the Examiner's assertion that no data exists showing that formulation nos. 658462-2 and 658463-3 readily break, this declaration points out that graphs depicting this data were inadvertently not attached to the August 18, 2003, declaration, but that a copy of these graphs is attached.

Regarding the Examiner's assertion that no data exists showing that Example 1 of the present application or CM 3/1 readily break, this declaration explains that Example 1 is "Reference P5" discussed in the July 24, 2002, declaration, so data has been provided for this invention composition. Regarding CM 3/1, this declaration states that the portion of the graph reflecting that this composition breaks is at 240 Pa. However, because CM 3/1 contains only 79.83% aqueous phase and, thus, is on the outer limits of the claimed invention, the breaking of this composition is more difficult to determine than for compositions containing more aqueous phase.

Regarding the Examiner's assertion that the reproduction of Mellul's compositions as CM 3/3, CM 3/4 and CM 3/5 was inappropriate because Mellul was not followed exactly, this declaration points out that Mellul's col. 7, line 57, and col. 8, line 6 indicate that glycerin and sodium chloride can be added to Mellul's compositions, so their addition to CM/3, CM/4 and CM/5 is appropriate. Moreover, this declaration explains that their presence or absence would not be expected to materially alter the properties of the resulting composition.

This declaration goes on to explain that KF 6015 was used instead of KF 6017 because Mellul indicates that these dimethicone copolyols are interchangeable and because KF 6015 was readily available. Finally, this declaration states that hydrocarbon surfactant found in Mellul's example 24 was not included in CM/3, CM/4 and CM/5 because Mellul's Tables I and II indicate that the presence of hydrogen surfactant results in a very unstable emulsion, whereas silicone surfactant results in a stable emulsion. The declarant notes that because they were attempting to create the most stable emulsion possible in accordance with Mellul's teachings, Mellul's hydrocarbon surfactant was not utilized.

Regarding the Examiner's assertion that given the data points provided it is not possible to determine if CM 3/5 has a break property at shear stress greater than 100 Pa, this declaration notes that it is impossible to apply a greater stress to CM 3/5 because this composition is too fluid, but that the cream-like compositions of the present invention are thicker, so more shear stress can be applied to them.

5. June 3, 2004: In response to the Examiner's assertion during the April 8, 2004, Interview that the claims were not commensurate in scope with the showings in the previously submitted declarations because the declarations did not show that compositions having 80% aqueous phase readily break, this declaration demonstrates that such compositions readily break.

Given this lengthy history, it is clear that no valid "reason of record" can exist.

Regarding (2), the invention composition is a water-in-oil (W/O) emulsion containing a dimethicone copolyol emulsifier comprising only oxyethylene groups as oxyalkylene groups, an aqueous phase of at least 80% by weight, and an oily phase to emulsifier weight ratio of greater than or equal to 5. As long as compositions satisfy these requirements, they should possess improved rheological and stability properties. According to the present specification, the type of oil present in the oil phase should not affect such properties: that is, any suitable oil could be used. (See, for example, page 7, line 13 et seq.). Accordingly, the claims are commensurate in scope with the submitted declarations, and the Examiner has offered no proof to the contrary for this untimely, baseless assertion.

Regarding (3), the declarations and present application demonstrate that the invention compositions possess "unexpected and surprising" rheological and stability properties. It is indisputable that the declarations relate to compositions.

In view of the above, Appellant respectfully submits that the present claims are in condition for allowance, and that the pending rejection should be REVERSED.

Each dependent claim similarly points out and describes a patentable invention neither disclosed nor suggested by the applied prior art. These claims themselves are separately patentable.

Claim 2 is a composition claim further requiring the presence of a physiologically acceptable medium. Nowhere does Mellul describe or allude to this additional characteristic of the claimed emulsions as being significant, nor does Mellul describe or suggest any benefits resulting from the presence of such a medium.

Claims 3, 10 and 17, each separately patentable as one is directed to a composition and the others to different methods, further require that the emulsions have a viscosity, measured using a Rheomat 180 viscometer at a shear rate of 200 s^{-1} and at 25°C , ranging from 0.15 Pa·s to 20 Pa·s. Nowhere does Mellul describe or allude to this additional characteristic of the claimed emulsions as being significant, nor does Mellul describe or suggest any benefits resulting from the use of such emulsions.

Claims 4, 11 and 18, each separately patentable as one is directed to a composition and the others to different methods, further specify that at least 70% by weight water be present. Nowhere does Mellul describe or allude to this additional characteristic of the claimed emulsions as being important, nor does Mellul describe or suggest any benefits resulting from the use of such emulsions.

Claims 5, 12 and 19, each separately patentable as one is directed to a composition and the others to different methods, further specify the amount of emulsifier present. Mellul does not teach or suggest emulsions having this specific amount of emulsifier present, or any benefits resulting from such emulsions.

Claims 6, 13 and 20, each separately patentable as one is directed to a composition and the others to different methods, further specify the amount of oily phase present. Mellul does not teach or suggest emulsions having this specific amount of oily phase present, or any benefits resulting from such emulsions.

Claims 7, 14 and 21, each separately patentable as one is directed to a composition and the others to different methods, further require the oily phase and emulsifier to be in a weight ratio of greater than or equal to 8. Mellul neither teaches nor suggests emulsions having the specified ratio, or any benefits associated with such emulsions.

Claims 8, 15 and 22, each separately patentable as one is directed to a composition and the others to different methods, further require the presence of one or more volatile silicone oils. Nowhere does Mellul describe or allude to this particular type of oil as being significant, nor does Mellul describe or suggest any benefits resulting from the use of such oils.

Claims 9 and 16, each separately patentable method claims, require specific application of the composition in claim 2. Mellul neither teaches or suggests using the claimed emulsions in such methods and, thus, these claims are free of the prior art.

Claims 23 and 24, each separately patentable, are composition claims further requiring the presence of a lower alcohol. Nowhere does Mellul describe or allude to this additional characteristic of the claimed emulsions as being significant, nor does Mellul describe or suggest any benefits resulting from the presence of such an alcohol.

Claims 25, 26 and 27, each separately patentable, are composition claims further requiring the presence of a polyol. Nowhere does Mellul describe or allude to this additional

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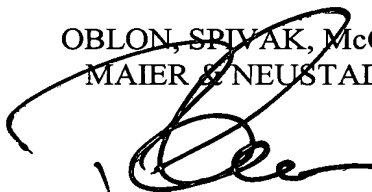
characteristic of the claimed emulsions as being significant, nor does Mellul describe or suggest any benefits resulting from the presence of such a polyol.

Claims 28 and 29, each separately patentable, are composition claims further requiring the presence of an electrolyte. Nowhere does Mellul describe or allude to this additional characteristic of the claimed emulsions as being significant, nor does Mellul describe or suggest any benefits resulting from the presence of such an electrolyte.

Accordingly, in view of the above remarks and reasons explaining the patentable distinctness of the presently appealed claims over the applied prior art, Appellant requests that the Examiner's rejections all be REVERSED.

Respectfully submitted,

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APPENDIX

1. (Original): A water-in-oil emulsion, comprising an aqueous phase dispersed in an oily phase with the aid of a silicone emulsifier, wherein:

(1) said aqueous phase is present in an amount of at least 80% by weight relative to the total weight of said oil-in-water emulsion;

(2) said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 5; and

(3) said emulsifier is a dimethicone copolyol comprising only oxyethylene groups as oxyalkylene groups.

2. (Original): A composition, comprising, in a physiologically acceptable medium, an aqueous phase dispersed in an oily phase with the aid of a silicone emulsifier, wherein:

(1) said aqueous phase is present in an amount of at least 80% by weight relative to the total weight of said composition;

(2) said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 5; and

(3) said emulsifier is a dimethicone copolyol comprising only oxyethylene groups as oxyalkylene groups.

3. (Original): The composition according to Claim 2, which has a viscosity, measured using a Rheomat 180 viscometer at a shear rate of 200 s^{-1} and at 25°C , ranging from 0.15 Pa·s to 20 Pa·s.

4. (Previously Presented): The composition according to Claim 2, which comprises at least 70% by weight water relative to the total weight of the composition.

5. (Original): The composition according to Claim 2, wherein said emulsifier is present in an amount ranging from 0.5% to 6% by weight relative to the total weight of the composition.

6. (Original): The composition according to Claim 2, wherein said oily phase is present in an amount ranging from 10% to 18% by weight relative to the total weight of the composition.

7. (Previously Presented): The composition according to Claim 2, wherein said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 8.

8. (Original): The composition according to Claim 2, wherein said oily phase comprises one or more volatile silicone oils.

9. (Original): A method for treating, protecting, caring for, removing make-up from and/or cleansing the skin, the lips and/or the hair, and/or for making up the skin and/or the lips, said method comprising:

applying a composition, comprising, in a physiologically acceptable medium, an aqueous phase dispersed in an oily phase with the aid of a silicone emulsifier, wherein:

(1) said aqueous phase is present in an amount of at least 80% by weight relative to the total weight of said composition;

(2) said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 5; and

(3) said emulsifier is a dimethicone copolyol comprising only oxyethylene groups as oxyalkylene groups to the skin, the lips and/or the hair of a subject in need thereof.

10. (Original): The method of Claim 9, wherein said composition has a viscosity, measured using a Rheomat 180 viscometer at a shear rate of 200 s^{-1} and at 25°C , ranging from $0.15 \text{ Pa}\cdot\text{s}$ to $20 \text{ Pa}\cdot\text{s}$.

11. (Previously Presented): The method of Claim 9, wherein said composition comprises at least 70% by weight water relative to the total weight of the composition.

12. (Original): The method of Claim 9, wherein said emulsifier is present in an amount ranging from 0.5% to 6% by weight relative to the total weight of the composition.

13. (Original): The method of Claim 9, wherein said composition comprises said oily phase in an amount ranging from 10% to 18% by weight relative to the total weight of the composition.

14. (Original): The method of Claim 9, wherein in said composition said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 8.

15. (Previously Presented): The method of Claim 9, wherein in said composition said oily phase comprises one or more volatile silicone oils.

16. (Original): A method for treating, protecting, caring for, removing make-up from, making up, and/or cleansing greasy skin, said method comprising:

applying a composition, comprising, in a physiologically acceptable medium, an aqueous phase dispersed in an oily phase with the aid of a silicone emulsifier, wherein:

(1) said aqueous phase is present in an amount of at least 80% by weight relative to the total weight of said composition;

(2) said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 5; and

(3) said emulsifier is a dimethicone copolyol comprising only oxyethylene groups as oxyalkylene groups to greasy skin of a subject in need thereof.

17. (Original): The method of Claim 16, wherein said composition has a viscosity, measured using a Rheomat 180 viscometer at a shear rate of 200 s^{-1} and at 25°C , ranging from 0.15 Pa·s to 20 Pa·s.

18. (Previously Presented): The method of Claim 16, wherein said composition comprises at least 70% by weight water relative to the total weight of the composition.

19. (Original) The method of Claim 16, wherein said emulsifier is present in an amount ranging from 0.5% to 6% by weight relative to the total weight of the composition.

20. (Original): The method of Claim 16, wherein said composition comprises said oily phase in an amount ranging from 10% to 18% by weight relative to the total weight of the composition.

21. (Original): The method of Claim 16, wherein in said composition said oily phase and said emulsifier are present in a weight ratio of said oily phase to said emulsifier greater than or equal to 8.

22. (Previously Presented): The method of Claim 16, wherein in said composition said oily phase comprises one or more volatile silicone oils.

23. (Previously Presented): The composition according to Claim 1, further comprising at least one lower alcohol.

24. (Previously Presented): The composition according to Claim 1, further comprising ethanol.

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25. (Previously Presented): The composition according to Claim 1, further comprising at least one polyol.

26. (Previously Presented): The composition according to Claim 1, further comprising glylcerol.

27. (Previously Presented): The composition according to Claim 1, further comprising propylene glycol.

28. (Previously Presented); The composition according to Claim 1, further comprising at least one electrolyte.

29. (Previously Presented): The composition according to Claim 1, further comprising sodium chloride.